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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,083	07/31/2003	Hartmut Strobel	DEAV2002/0057 US NP	2215

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EXAMINER

POWERS, FIONA

ART UNIT PAPER NUMBER

1626

DATE MAILED: 09/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/632,083

Applicant(s)

STROBEL ET AL.

Examiner

Fiona T. Powers

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-9 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1 to 7, drawn to compounds and pharmaceutical compositions, classified in classes 544, 546, 548 and 549, various subclasses.
- II. Claim 8, drawn to a method for the stimulation of the expression of endothelial NO synthase, classified in class 514, various subclasses.
- III. Claim 9, drawn to a method for the treatment of various diseases, classified in class 514, various subclasses.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II or III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product as note the various methods of use and diseases recited in claims 8 and 9.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for one of the groups is not required for the other groups, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Additionally, it would be an undue burden on the examiner and the patent office resources if all of the claims were examined in a single application as different patent, literature and computer searches would need to be done.

Claims 1 to 7 are drawn to more than one patentably distinct (under 35 U.S.C. 121 area of invention, joined together via means of "Markush" type claims, and accordingly, election of a single species is required as per the provisions of MPEP 803.02.

The claims as presented contain such a vast multitude of possible compounds due to the "possibilities and permutations"

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that are present that it is not possible to identify each and every species encompassed by the claims. Accordingly, to facilitate election, applicants are required to elect a single specific compound and upon such election the Examiner will review the claims and indicate (a) which compounds are so similar thereto as to be part of the elected matter and, (b) by such indication (i.e. by exclusion) which compounds are drawn to non-elected subject matter. Further, whatsoever compounds are treated together so too will compositions containing such active compound(s) also be part of the elected subject matter. . With the election of a specific exemplified compound, an inventive group, including the corresponding composition will be identified by the examiner as the inventive group for the examination.

It is considered that the "Markush" type claims encompassing such species are directed to multiple independent and distinct inventions since the species encompass compounds that are so unrelated and diverse that a prior art reference anticipating the claims with respect to one of the species will not render the claims obvious under 35 U.S.C. 103 with respect to any of the other species. Further, these claims encompass species that are considered to be independent since they are unconnected in operation, one does not require the others for

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ultimate use and the specification does not disclose a dependent relationship between them. Moreover, there are encompassed species that are considered to be distinct from others on the basis of their properties. Thus, this application contains species that are capable of supporting separate patents under 35 U.S.C. 121.

Accordingly, applicants are now required to make a provisional election of a single independent and distinct species of compound as noted supra, prior to the examination of said claims on the merits. This election will be given the effect in the event that the Markush type claim(s) is (are) not found allowable, at which time the examination of the claims presented will be limited to the Markush type claim(s) directed solely to the elected species, with claims directed to the nonelected species being held withdrawn from further consideration. It should be noted that an election of species has been held to be tantamount to a requirement for restriction (In re Herrick, 1958 C.D. 1 and In re Joyce, 1958 C.D. 2) and enjoys the benefit of 35 U.S.C. 121.

Applicants' response must include a provisional election even though the requirement be traversed (37 CFR 1.142 and 1.143). Applicants are also advised that any traversal must be supported by specific argument(s) in order to perfect the right

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to petition in the event that the provisional requirement is given effect in the event noted supra. Applicants are also advised that arguments adequate to cause withdrawal of this requirement would warrant the ultimate conclusion that all species are patentably indistinct and a reference for one species would be considered a reference as to all species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must

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be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fiona T.

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Powers whose telephone number is 571-272-0702. The examiner can normally be reached on Monday - Friday 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Fiona T. Powers
Fiona T. Powers
Primary Examiner
Art Unit 1626

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September 19, 2005